13 October 2016
EMA/CHMP/625736/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Trisenox

arsenic trioxide

On 13 October 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Trisenox. The marketing authorisation holder for this medicinal product is Teva B.V.

The CHMP adopted changes to the existing indication as follows[2]:

''Trisenox is indicated for induction of remission~~,~~ and consolidation in adult patients with ~~relapsed~~:

- **Newly diagnosed low-to-intermediate risk acute promyelocytic leukaemia (APL) (white blood cell count, ≤ 10 x 10^3/µl) in combination with all-*trans*-retinoic acid (ATRA)**
- **Relapsed/**refractory acute promyelocytic leukaemia (APL) **(previous treatment should have included a retinoid and chemotherapy)**

characterised by the presence of the t(15;17) translocation and/or the presence of the Pro-Myelocytic Leukaemia/Retinoic-Acid-Receptor-alpha (PML/RAR-alpha) gene. ~~Previous treatment should have included a retinoid and chemotherapy.~~

The response rate of other acute myelogenous leukaemia subtypes to ~~Trisenox~~ **arsenic trioxide** has not been examined.''

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

[2] New text in bold, removed text as strikethrough

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